MAR 0 4 2003

Company:

Vidar Systems Corporation
460 Springpark Place
Herndon, VA 20170

Contact:

MEDIcept
200 Homer Ave
Ashland, MA 01721
F. David Rothkopf

Date Prepared:

December 4, 2002

Name of Device:

VIDAR Bone Track System Software

Predicate Device:

Agfa IMPAX OT3000 Orthopedic Display Station

Intended Use:

Bone Track software provides pre-operative digital implant templating to facilitate the selection and ordering of orthopedic implants. The software allows for a semi-automatic ordering process, by printing a pick list, which can be used by the physician to order orthopedic components directly from the manufacturer. The software also tracks those components and provide post-operative patient follow-up all in a digital environment. The software will be provided on a stand-alone or hospital network workstation.

Device Description:

The VIDAR Bone Track System is comprised of three modules: The Pre-Operative Module, the Tracking Module and the Post-Operative Module

In the Pre-Operative Module, the patient's digital x-ray is then loaded into the software, either from the hospital network, via a disk or from a digital scanner. The x-ray image is located in the system using standard digital measuring tools. The physician chooses which orthopedic device to template. The user then utilizes the software tools to overlay pre-loaded digital templates onto the x-ray image to allow for proper prosthetic selection. Once the physician has selected all of the appropriate prosthetic components, the software generates a pick list to allow for easy ordering of parts. This list can be printed out.

The VIDAR Bone Track System allows for tracking of orthopedic devices used during patient surgery. Using a PDA and a bar code reader, the devices' bar codes are scanned. Device manufacturer, device part number, lot number, and serial number are captured.

The VIDAR Bone Track System's Post-Operative Module allows the physician to track migration or other changes to the implant in the bones' structures for a specific patient over time using industry-accepted algorithms. The physician can use measurements include stem dislocation, wear circle cup and wear elliptic cup. Bone Track is not a diagnostic tool. It is to be used by the physician as an assistance tool.

Technological Characteristics:

The technological characteristics of the new device are the same as those of the predicate device.

Performance Data:

Bench testing was performed to ensure that the device performs as intended. All testing demonstrated satisfactory performance of the device.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Mr. F. David Rothkopf
MEDIcept
for Vidar System Corporation
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K024171
Trade Name: Vidar Bone Track System Software
Regulation Number: 21 CFR 892.1750, 21 CFR 888.4800
Regulation Name: Computed Tomography/X-Ray System, Template for Clinical Use
Regulatory Class: II
Product Code: JAK, HWT
Dated: December 16, 2002
Received: December 18, 2002

Dear Mr. Rothkopf:

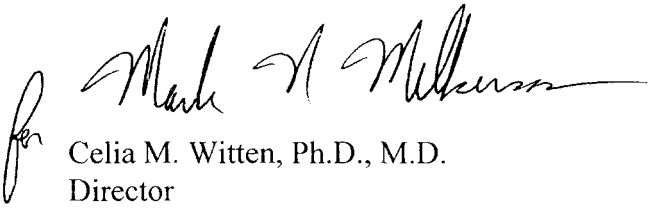
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K024171

Device Name: Vidar Bone Track System Software

Indications For Use:

Bone Track software provides pre-operative digital implant templating to facilitate the selection and ordering of orthopedic implants. The software allows for a semi-automatic ordering process, by printing a pick list, which can be used by the physician to order orthopedic components directly from the manufacturer. The software also tracks those components and provide post-operative patient follow-up all in a digital environment. The software will be provided on a stand-alone or hospital network workstation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

Division Sign-Off
Division of General, Restorative
and Neurological Devices

510(k) Number K024171